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Joan Claybrook, President

EXECUTIVE SECRETARIAT

February 3, 2000

Jane Henney, M.D.
Commissioner, Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Final FDA Regulations on Claims Made for Dietary Supplements Concerning the
Effect of the Product on the Structure or Function of the Body

Dear Commissioner Henney,

We are writing to urge that you immediately make important changes concerning uses during pregnancy, in the final rule concerning dietary supplements, published on January 6, 2000. The rule is scheduled to go into effect on February 7, 2000.

The rule categorizes "ordinary morning sickness" and "leg edema associated with pregnancy" as common conditions that are not "diseases." Under the Dietary Supplement Health Education Act (DSHEA), that categorization allows dietary supplement manufacturers to promote products as treatments of those conditions without first proving that the products are safe and effective. We strongly disagree with that categorization. Both morning sickness and edema of pregnancy, when uncomfortable enough to cause a woman to use a substance for relief of symptoms, are severe enough to be considered diseases. We urge you to immediately amend the rule explicitly to include morning sickness and edema of pregnancy as diseases.

The final rule bundles these pregnancy-related conditions with "mild symptoms associated with normal life stages or processes." 65 Fed. Reg. 1020. The other stages or processes in this category are adolescence, the menstrual cycle, menopause, and aging. Pregnancy differs from the other items listed, however, in that those stages and processes are inevitable and unavoidable aspects of being a human or, more specifically, a woman. Pregnancy's difference is that no healthy, normal woman will become pregnant without an outside intervention, although she will enter adolescence, have a menstrual cycle, go through menopause, and age. Accordingly, bundling pregnancy with these life stages or processes is not reasonable.

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Ralph Nader, Founder

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Moreover, morning sickness and edema of pregnancy, when severe enough to cause a woman to seek treatment, cannot be considered "normal." Rather, in that circumstance, the condition could very well be one that could cause "significant or permanent harm." For example, edema of pregnancy could well be an early symptom of pre-eclampsia or other types of toxemias of pregnancy which, if undiagnosed and not properly treated, can jeopardize the health of both the mother and infant. Thus, even if pregnancy were properly categorized as a "life stage or process" comparable to adolescence or menopause—which it is not—these conditions would be diseases, under the FDA's own reasoning. See 65 Fed. Reg. 1020.

As you are well aware, substances or viruses of little consequence to the mother can have profoundly harmful effects on the developing embryo and fetus. Thalidomide, although effective as a sleeping pill for the expectant mother, can cause very substantial birth defects when taken in the first trimester of pregnancy. Another example, the congenital rubella syndrome that can cause blindness, birth defects and mental retardation, is caused by a rather mild rubella infection of the mother during the first trimester. Thus, products that are safe for an adult woman herself may have profoundly adverse effects on a developing embryo and fetus.


The cause of most birth defects remains unknown. The best evidence suggests that many birth defects are caused by agents that humans have consumed for hundreds of years. For example, in the early 1970s, we learned that alcohol can cause severe physical and mental birth defects. Although we do not have the evidence to identify which dietary supplements have been and continue to cause birth defects, it is reasonable to assume that humans are now consuming such agents. A government regulation that facilitates consumption by pregnant women of such agents, which have not been tested for their adverse effects on the fetus, will unfortunately put embryos and fetuses at risk.

In sharp contrast, chemicals that are classified as drugs must undergo rigorous scrutiny, before marketing approval, for any adverse effects on reproduction, including fetal toxicity. As a result, data are available to allow such drugs to be categorized into one of several categories concerning risk of use during pregnancy. Currently, 81 drugs are listed in FDA Pregnancy Category X, defined as: "Studies in animals or humans demonstrate fetal abnormalities or adverse reaction reports indicate evidence of fetal risk. The risk of use in a pregnant woman clearly outweighs any possible benefit." Included on this list are such chemicals as Vitamin A, ephedrine, and caffeine—all of which are found, not infrequently, in herbal preparations or dietary supplements. When sold as herbals or food supplements, these three chemicals sometimes, but not always have a pregnancy warning. Because DSHEA does not allow the FDA to require the kinds of studies that would produce evidence to categorize other food supplements or herbals into safe or unsafe categories for use in pregnancy, claims for morning sickness or edema of pregnancy will be unaccompanied by any assurance that the products will not cause birth defects or other kinds of fetal toxicity.

Ironically, almost 40 years ago the FDA won worldwide acclaim by keeping

thalidomide, a drug used to treat morning sickness in pregnant women, off the U.S. market. By this action, the FDA saved hundreds if not thousands of American children from being born with severe birth defects. Now, the same agency seems to have thrown caution to the wind and appears willing to endanger unborn babies by pretending that medical conditions such as morning sickness and edema of pregnancy are not diseases, thereby allowing the marketing of dietary supplements/herbals that have not been tested for safety. We simply cannot believe that the agency has really considered the consequences of this aspect of the final rule. We therefore urge you immediately to revoke those parts of the rule that reclassify as non-diseases morning sickness and edema of pregnancy. We appreciate your prompt reply to this urgent request.

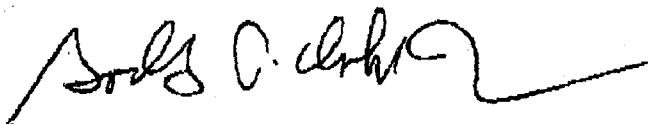
Sincerely,



Sidney M. Wolfe, M.D.

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